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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,508	11/07/2001	Beerelli Seshi	0152.00418	8090

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EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,508	SESHI, BEERELLI	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

d for Reply

SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM HE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

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1)☒ Responsive to communication(s) filed on *19 March 2004*.

a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

sposition of Claims

4)☒ Claim(s) *63-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The **examiner** of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michail Belyavskyi, Group Art Unit 1644, Technology Center 1600

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/19/2004 has been entered.

Claims 63-100 are pending.

3. Applicant asserts that claims 63-89 were "previously presented".

It is noted however, that previously only claims 1-62 were pending and they were all cancelled by Applicant's amendment filed 03/19/2004. Newly submitted claims are 63-100.

Newly submitted claims 87-89 and 92-100 will be examined as they reads on the elected invention of Group I, claims 22-24, now claims 63-100 i.e. an isolated pluri-differentiated mesenchymal progenitor cell and a plurality of said isolated pluri-differentiated mesenchymal progenitor cell of the same type and a therapeutic composition comprising said cells.

Claims 63-100 reads an isolated pluri-differentiated mesenchymal progenitor cell and a plurality of said isolated pluri-differentiated mesenchymal progenitor cell of the same type and a therapeutic composition comprising said cells are under consideration in the instant application.

4. The disclosure is objected to because it contains an embedded hyperlink on page 23, lines 25-30 and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. Applicant's cancellation of Claims 42-61 in conjunction with Applicant's Declaration under 37 C.F.R. 1.132 by Dr. Seshi has obviated the rejections of record in the previous Office Action mailed on 10/10/2003.

The New Grounds of Rejection are set forth herein.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e2) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

7. Claims 63-100 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,226,914 or US Patent 5,811,094 each as is evidenced by the Dictionary of Cell Biology (ed. Lackie et al, 1989, Academic Press, Harcourt Brace Jovanovich, page 189).

US Patent '914 teaches an isolated plurality of pluri-potential human mesenchymal progenitor cells from bone marrow (see entire document, Abstract and column 1 in particular). US Patent '914 teaches that said cells can further differentiated into various specific cell lineage, including muscle cell, osteoblast and fibroblast and adipocytes see overlapping columns 3 and 4 in particular). US Patent '914 teaches an isolated pluri-potential human mesenchymal progenitor that are obtained directly form primary cell culture, i.e. not a cells of a cell line, by removing macrophages from said culture and fractionating and collecting the remaining cells. (see overlapping columns 5-7 in particular). US Patent '914 teaches a pharmaceutical composition comprising said cells wherein pharmaceutically acceptable carrier is sterile (see column 10 in particular).

Similarly, US Patent 5,811,094 teaches an isolated plurality pluri-potential human mesenchymal progenitor cells from bone marrow (see entire document, Abstract and column 1 in particular). US Patent '094 teaches that said cells can further differentiated into various specific cell lineage, including muscle cell, osteoblast and fibroblast and adipocytes see overlapping columns 2 and 3 in particular). US Patent '094 teaches an isolated pluri-potential human mesenchymal progenitor that are obtained directly form primary cell culture, i.e. not a cells of a cell line, by removing macrophages from said culture and fractionating and collecting the remaining cells. (see overlapping columns 7-8 and 12 in particular). US Patent '094 teaches a pharmaceutical

composition comprising said cells wherein pharmaceutically acceptable carrier is sterile (see columns 18 and overlapping column 47-48 in particular).

As is evidenced by the Dictionary of Cell Biology, pluri-potential progenitor cells refers to the single cell type capable of differentiation into several final differentiated types, i.e. capable of simultaneously co-expressing genes specific for multiple lineages. It is noted that the instant Specification defines "pluri-differentiated" cell as cell co-expressing genes specific for multiple lineages (See page 12 of the Specification as filed).

Claims 64-68, 74-78, 88- 94 and 100 are included because the claimed functional limitation would be inherent properties of the referenced cell and the pharmaceutical composition comprising said cells because the reference cells are the same cells, i.e. human mesenchymal progenitor cell that were obtained from the same sources as claimed cells, therefore the referenced cells would inherently: (i) comprise at least four different mesenchymal cell linearge markers comprises adipocyte, osteoblast, fibroblast and muscle cells as claimed in claims 64and 88 and (ii) expresses a markers specific for a single cell lineage, as claimed in claims 65, 75 and 100; (iii) be not a neoplastic and chromosomally normal as claimed in claims 67, 68, 77, 78, 93 and 94 . Since the office does not have a laboratory to test the reference cells, it is applicant's burden to show that the reference cell do not have the same functional limitation as as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claims 71, 72, 81, 82, 97 and 98 are included because the recited isolated mesenchymal progenitor cells and a pharmaceutical composition comprising said cells are the same cells and pharmaceutical composition as claimed irrespective of a culture medium in the absence of shown structurally different properties. It is noted that the instant claims recited a process of producing an isolated pluri-differentiated mesenchymal progenitor cells that is different from the referenced process of producing an isolated pluri-differentiated mesenchymal progenitor cells. However, the instant claims are drawn to a product (an isolated pluri-differentiated mesenchymal progenitor cell) and the patentability of the product does not depend on its method of production. In re Thrope,227 USPQ 964,966 (Fed. Cir. 1985). See MPEP 2113.

The reference teaching anticipates the claimed invention.

8. Claims 63-100 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,149,902 as is evidenced by the Dictionary of Cell Biology (ed. Lackie et al, 1989, Academic Press, Harcourt Brace Jovanovich, page 189).

US Patent '902 teaches an isolated pluri-potential human mesenchymal progenitor cells from bone marrow and a pharmaceutical composition comprising said cells (see entire document, Abstract and columns 5 and 14 in particular). US Patent '902 teaches an isolated pluri-potential human mesenchymal progenitor that are obtained directly form primary cell culture, i.e. not a cells of a cell line, by removing macrophages from said culture and fractionating and collecting the remaining cells. (see columns 20,21 and 22 in particular). US Patent '914 teaches a pharmaceutical composition comprising said cells wherein pharmaceutically acceptable carrier is sterile (see column 27 in particular).

As is evidenced by the Dictionary of Cell Biology, pluri-potential progenitor cells refers to the single cell type capable of differentiation into several final differentiated types, i.e. capable of simultaneously co-expressing genes specific for multiple lineages. It is noted that the instant Specification defines "pluri-differentiated" cell as cell co-expressing genes specific for multiple lineages (See page 12 of the Specification as filed).

Claims 64-68, 74-78, 88- 94 and 100 are included because the claimed functional limitation would be inherent properties of the referenced cell and the pharmaceutical composition comprising said cells because the reference cells are the same cells, i.e. human mesenchymal progenitor cell that were obtained from the same sources as claimed cells, therefore the referenced cells would inherently: (i) comprise at least four different mesenchymal cell linearge markers comprises adipocyte, osteoblast, fibroblast and muscle cells as claimed in claims 64and 88 and (ii) expresses a markers specific for a single cell lineage, as claimed in claims 65, 75 and 100; (iii) be not a neoplastic and chromosomally normal as claimed in claims 67, 68, 77, 78, 93 and 94 . Since the office does not have a laboratory to test the reference cells, it is applicant's burden to show that the reference cell do not have the same functional limitation as as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claims 71, 72, 81, 82, 97 and 98 are included because the recited isolated mesenchymal progenitor cells and a pharmaceutical composition comprising said cells are the same cells and pharmaceutical composition as claimed irrespective of a culture medium in the absence of shown structurally different properties. It is noted that the instant claims recited a process of producing an isolated pluri-differentiated mesenchymal progenitor cells that is different from the referenced process of producing an isolated pluri-differentiated mesenchymal progenitor cells. However, the instant claims are drawn to a product (an isolated pluri-differentiated mesenchymal progenitor cell) and the patentability of the product does not depend on its method of production. In re Thrope,227 USPQ 964,966 (Fed. Cir. 1985). See MPEP 2113.

The reference teaching anticipates the claimed invention.

9. No claim is allowed.

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 25, 2004

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